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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/715,969	11/18/2003	James D. Ralph	F-305	5368
36402	7590	10/06/2004	EXAMINER	
SPINECORE, INC.			BLANCO, JAVIER G	
447 SPRINGFIELD AVENUE			ART UNIT	
SUITES W2-W3			PAPER NUMBER	
SUMMIT, NJ 07901			3738	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/715,969

Applicant(s)

RALPH ET AL.

Examiner

Javier G. Blanco

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Manasas et al. (US 6,520,996 B1).

As seen in Figures 1-3, Manasas et al. disclose an intervertebral spacer device (implant 10) comprising first and second plate members (characters 100 and 102) and at least one arched strip spring restoring force providing element (torsional support 300) disposed between the first and second plate members, and disposed such that a compressive load applied to the external faces of said plates is counteracted by said at least one restoring force providing element (see entire document). It should be noted that torsional support 300 are curved/arched struts acting as a spring (see column 8, lines 27-29) and will provide flexibility and resistance both to torsion and to bending of implant 10 (see entire document). It should also be noted that struts 300 would inherently support compressive loads as well as torsional loads.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3738

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al. (US 5,989,291 A) in view of Manasas et al. (US 6,520,996 B1).

As seen in Figures 6-9, Ralph et al. disclose the claimed structure of the intervertebral spacer device comprising first and second plate members, and at least one arch-shaped spring element (see also entire document; see claims 1 and 7-10). Although Ralph et al. disclose "the internal structure of the present invention comprises a spring member, or other equivalent subassembly which provides a restoring force when compressed" (see column 3, lines 26-29), they did not particularly disclose the spring element as an arched strip (emphasis added) spring element.

However, Manasas et al. disclose an intervertebral spacer device (see rejection above) comprising at least one arched strip spring element in order to provide flexibility and resistance both to torsion and to bending of the intervertebral spacer device. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising at least one arched strip spring element, as taught by Manasas et al., with the intervertebral spacer device of Ralph et al., in order to provide flexibility and resistance both to torsion and to bending of the intervertebral spacer device.

*Response to Arguments*

5. Applicant's arguments filed July 9, 2004 have been fully considered but they are not persuasive.

a. Regarding 102(e) rejection over Manasas et al. '996 (and 103(a) rejection over Ralph et al. '201 in view of Manasas et al. '996), Applicant argue that "given the foregoing specific description of the claim term "arched strip spring" by the Applicants in the specification, Manasas et al. cannot anticipate the invention as claimed in claim 1." Applicants also argue: "Manasas et al. specifically states torsional supports 300 cannot act as supporting compressive loads". Examiner respectfully disagrees.

(i) Under M.P.E.P. 2113.03, the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

(ii) The limitations on which the Applicants rely (i.e., "having flat ends and a curvate central portion", "mounted to a first plate surface at the lateral ends of the strip and the peaks of the arches are fixed to the opposing plate") are not stated in the claims. It is the claims that define the claimed invention, and it is claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.* 7 USPQ2d 1064.

(iii) The dictionary definition of "compressive" is: "of or relating to compression". The term "compression" is defined as: "the act, process, or result of pressing or squeezing together". Manasas et al. '996 disclose "torsional supports 300a, 300b" **(a)** to provide resistance to bending and/or torsion (see column 7, lines 52-65), **(b)** to perform some of the shock absorbing function that the replaced joint had (see column 8, lines 7-10), and **(c)** to act as a spring (see column 8,

Art Unit: 3738

lines 24-27). By the dictionary definition of "compressive", Manasas et al. '996 teachings clearly show "arched strip spring(s)" as counteracting a "compressive load applied to the external surface" of the plate members.

### *Conclusion*

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Hedman et al. (US 4,759,769), Harrington (US 5,893,889), Cauthen (US 6,440,168), Kuslich et al. (US 2003/0083749), Beaurain et al. (FR 2 824 261), and Manasas et al. (WO 01/93786).

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

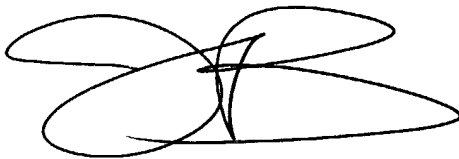
Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

September 30, 2004

A stylized handwritten signature consisting of a large loop on the left and a series of overlapping loops on the right.A handwritten signature in cursive script, appearing to read 'David H. Willse'.

David H. Willse  
Primary Examiner